IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Entitled	:	CARDIAC DEVICES AND METHODS FOR MINIMALLY INVASIVE REPAIR OF ISCHEMIC MITRAL REGURGITATION
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AMENDMENT AFTER FINAL OFFICE ACTION FILED
WITH REQUEST FOR CONTINUED EXAMINATION

SIR:

This paper is filed in response to the Final Office Action dated October 22, 2009 (the "Final Office Action") for the above-identified application, and is being filed with a Request for Continued Examination. Initially, please amend the application, and consider the remarks as provided herein below.

In The Claims:

Please amend claims 1, 64 and 69, and add new claims 70-73, as indicated herein below in the associated claim listing provided on separate sheets:

1. (Currently Amended) An apparatus for treating atrioventricular valve regurgitation, comprising:

a cutting arrangement configured to sever at least one chord attaching an atrioventricular leaflet to an internal cardiac muscle;

a positioning catheter configured to position the cutting arrangement proximate the at least one chord; and

a grasping arrangement which is separate from the cutting arrangement, and which is configured to at least partially constrain a movement of the at least one chord relative to the catheter,

wherein the catheter comprises an opening in which the grasping arrangement constrains the movement of the at least one chord and ~~through~~ in which the cutting arrangement is ~~provided~~ configured to sever the at least one chord.

2. (Previously Presented) The apparatus of claim 1, wherein the cutting instrument comprises a blade having a cutting edge width that is approximately the same size as a diameter of the at least one chord.

3. (Withdrawn) The apparatus of claim 1, wherein the cutting instrument comprises an optical fiber for delivering ablative laser energy.

4. (Withdrawn) The apparatus of claim 1, wherein the cutting instrument comprises a radiofrequency electrode.

5. (Withdrawn) The apparatus of claim 1, wherein the catheter has a curved end suitable to allow engagement of chords attached to a posterior leaflet.

6. (Withdrawn) The apparatus of claim 1, wherein the catheter includes a steerable tip.

7. (Withdrawn) The apparatus of claim 6, wherein the catheter further comprises coaxial steering wires for steering the catheter tip.

8. (Withdrawn) The apparatus of claim 1, wherein the cutting instrument is reversibly extendable through the opening, the opening being located at the end of the catheter proximate the at least one chord.

9. (Withdrawn) The apparatus of claim 1, wherein the opening comprises a notch in the catheter having a cross-sectional notch area greater than the cross-sectional area of the at least one chord.

10. (Withdrawn) The apparatus of claim 9, wherein the notch includes at least one protruding edge defining a portion of the notch for limiting motion of the at least one chord when positioned within the notch.

11. (Withdrawn) The apparatus of claim 1, wherein the cutting instrument further comprises a means for grasping the at least one chord.

12. (Withdrawn) The apparatus of claim 11, wherein the means comprises a wire having a deformed end for partially encompassing the at least one chord.

13. (Withdrawn) The apparatus of claim 12, wherein the wire is composed of a shape memory material that deforms at or near body temperature.

14. (Withdrawn) The apparatus of claim 11, wherein the grasping means is reversibly extendable through the opening, the opening being located at the end of the catheter proximate the at least one chord, so as to retract a grasped chord toward the opening.

15. (Withdrawn) The apparatus of claim 1, further comprising a pair of operable jaws disposed at the end of the positioning catheter proximate the at least one chord for grasping the at least one chord.

16. (Withdrawn) The apparatus of claim 1, further comprising a pair of pivoting pincers disposed at the end of the positioning catheter proximate the at least one chord for pinioning the at least one chord in a closed position.

17. (Withdrawn) The apparatus of claim 1, further comprising an introducer catheter for advancing the positioning catheter toward the at least one chord.

18. (Withdrawn) The apparatus of claim 17, wherein the introducer catheter further comprises a directing arm through which the positioning catheter is maneuvered to the

position proximate the at least one chord.

19. (Withdrawn) The apparatus of claim 17, wherein the introducer catheter further comprises a means for temporarily stabilizing the position of the introducer catheter within the LV.

20. (Withdrawn) The apparatus of claim 19, wherein the stabilization means comprises:

one or more contact elements reversibly extendable from the introducer catheter so as to contact an internal surface of the heart cavity at one or more points.

21. (Withdrawn) The apparatus of claim 20, wherein the contact element is composed of a shape memory elastic material that assumes the shape desired upon extension from the introducer catheter.

22. (Withdrawn) The apparatus of claim 17, further comprising an ultrasound transducer for imaging a region proximate the at least one chord located on the introducer catheter.

23. (Withdrawn) The apparatus of claim 17,

wherein the positioning catheter protrudes from within the introducer catheter through an opening in the introducer catheter; and

further comprising a plurality of positioning wires similarly disposed within and protruding from the introducer catheter, the positioning wires attached to the positioning catheter so as to enable steering of the end of the positioning catheter by selectively tensioning on one or more of the wires.

24. (Withdrawn) The apparatus of claim 17, wherein the introducer catheter further comprises an imaging device oriented so as to image a region near the mitral valve including the at least one chord

25. (Withdrawn) The apparatus of claim 24, wherein the imaging device is comprised of a imager selected from the group consisting of: a two-dimensional matrix array of piezoelectric crystals, a linear phased array and means for rotating the array within the catheter so as to produce a three-dimensional image, a magnetic resonance coil, and fiber optics for transmitting and receiving near infrared energy.

26. (Withdrawn) Method of treating atrioventricular valve regurgitation related to restricted leaflet closure by leaflet tethering, comprising the step of:

percutaneously severing at least one chord attaching an atrioventricular leaflet to an internal cardiac muscle.

27. (Withdrawn) The method of claim 26, further comprising step of:

grasping the at least one chord prior to severing.

28. (Withdrawn) The method of claim 26, wherein the at least one chord is a basal chord.

29. (Withdrawn) The method of claim 26, wherein the at least one chord comprises two chords, wherein a first one of the chords attaches to an anterior leaflet, and a second one of the chords attaches to a posterior leaflet.

30. (Withdrawn) The method of claim 26, wherein the at least one chord comprises a pair of chords.

31. (Withdrawn) The method of claim 30, wherein the pair of chords comprises two chords of an anterior leaflet closest to the central axis of the ventricle.

32. (Withdrawn) The method of claim 26, further comprising the step of:
positioning a cutting device proximate the at least one chord via a catheter.

33. (Withdrawn) The method of claim 32, wherein the positioning step includes advancing the cutting device via a pathway selected from the group consisting of: retrograde via the aterial system into the left ventricle, through the venous system and right atrium into the left atrium across the atrial septum, directly through a wall of the heart, and percutaneously through a small incision in the chest wall and pericardium.

34. (Withdrawn) The method of claim 32, wherein the advancing step is assisted through the percutaneous use of robotic tools.

35. (Withdrawn) The method of claim 26, further comprising steps of imaging a cardiac region including the at least one chord prior to and during the severing process.

36. (Withdrawn) The method of claim 35, wherein the imaging comprises transducing ultrasound energy to the region.

37. (Withdrawn) The method of claim 36, wherein the ultrasound energy is transduced from the chest surface, esophagus, or within the heart.

38. (Withdrawn) The method of claim 37, wherein the ultrasound energy transduced from within the heart is provided by an ultrasound transducer positioned proximate the at least one chord.

39. (Withdrawn) The method of claim 35, wherein the imaging comprises optically imaging the region through one or more optical fibers.

40. (Withdrawn) The method of claim 35, wherein an ultrasound transducer is similarly positioned proximate the at least one chord.

41-55 (Canceled).

56. (Previously Presented) The apparatus of claim 1, wherein the cutting arrangement is further configured to sever at least one chord while the grasping arrangement is at least partially constraining a movement of the at least one chord.

57. (Previously Presented) The apparatus of claim 1, wherein the grasping arrangement comprises a grasping member configured to slide along a longitudinal direction relative to an extension axis of the catheter.

58. (Previously Presented) The apparatus of claim 57, wherein the grasping member comprises a wire.

59. (Previously Presented) The apparatus of claim 58, wherein a distal end of the wire is curved.

60. (Previously Presented) The apparatus of claim 58, wherein a distal end of the wire comprises a hook-shaped portion.

61. (Previously Presented) The apparatus of claim 58, wherein the wire comprises a shape-memory material.

62. (Previously Presented) The apparatus of claim 1, wherein the grasping arrangement comprises at least one pincer member which is rotatably coupled to the catheter and which is configured to surround at least a portion of the at least one chord.

63. (Previously Presented) The apparatus of claim 1, wherein the grasping arrangement comprises at least two pincer members which are rotatably coupled to the catheter and which are configured to surround at least a portion of the at least one chord.

64. (Currently Amended) The apparatus of claim 1, further comprising a stabilizing arrangement configured to at least partially constrain a motion of the catheter relative to a location within a chamber of a heart and extend longitudinally ~~from~~ past an edge of the catheter to contact ~~an apex of~~ a ventricle.

65. (Previously Presented) The apparatus of claim 64, wherein the stabilizing arrangement comprises an extendable member which is configured to contact the location within the chamber.

66. (Previously Presented) The apparatus of claim 65, wherein the stabilizing arrangement comprises a shape memory material.

67. (Previously Presented) The apparatus of claim 1, further comprising a second catheter configured to advance the positioning catheter toward the at least one chord.

68. (Previously Presented) The apparatus of claim 1, wherein the grasping arrangement retracts the at least one chord into the catheter.

69. (Currently Amended) The apparatus of claim 6869, wherein the grasping arrangement retracts the at least one chord into the opening of the catheter, and wherein the cutting arrangement severs the at least one chord.

70. (New) The apparatus of claim 64, wherein the stabilizing arrangement is further configured to extend longitudinally to an apex of the ventricle with respect to an extension of the catheter.

71. (New) The apparatus of claim 1, wherein the cutting arrangement is further configured to sever the at least one chord only within the opening.

72. (New) The apparatus of claim 1, wherein the grasping arrangement and the cutting arrangement are longitudinally coupled to one another.

73. (New) The apparatus of claim 1, wherein the cutting arrangement is further configured to move only approximately in parallel with respect to a motion of the grasping arrangement to facilitate the severing of the at least one chord in the opening.

REMARKS

I. INTRODUCTION

Claims 1, 64 and 69 have been amended as provided herein above merely to remove minor informalities therefrom, clarify the subject matter recited therein and address the Examiner's comments, but not for any reasons related to the patentability thereof. Claims 3-40, which were previously indicated as being cancelled (without prejudice), are indicated in the claim listing provided herein above as being withdrawn, since these claims are drawn to particular species of a genus associated with at least one generic claim under examination in the above-identified application. New claims 71-73 have been added. Accordingly, claims 1, 2 and 56-73 are now under consideration in the above-identified application.

Provided herein above, please find a claim listing indicating the claim amendments, claim additions and current status of the claims on separate sheets so as to comply with the requirements set forth in 37 C.F.R. § 1.121. It is respectfully submitted that no new matter has been added. Support for the amendments to claims 1, 64 and 69, and for the addition of new claims 70-73, can be found in the originally-filed application, including the specification, drawings and/or claims thereof. (See, e.g., Specification of the above-identified application, paras. [0037] - [0039] and [0042], and Figures 4A and 4B).

Applicant thanks the Examiner for participating in an interview with the Applicant's representatives and Applicant on April 19, 2010 (the "Interview").

II. INTERVIEW SUMMARY

During the Interview, the rejection of claims 1, 56, 57 and 62-65 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,558,644 to Boyd et al. (hereinafter the "Boyd Patent"), the Boyd Patent, and the recitations of the pending claims were discussed. It was also discussed that claims 3-40, which were previously indicated as being cancelled (without prejudice), would be indicated in this submission as being withdrawn, since these claims are directed to particular species of a genus associated with at least one generic claim under examination in the above-identified application, which is believed to be on its way to being allowed.

In the Interview, Gary Abelev, Esq. and Randall M. Berman, Esq., representatives of the Applicant, and Applicant/inventor Dr. Robert A. Levine, discussed potential amendments to the claims with the Examiner to clarify the subject recited therein and to overcome the current rejection under 35 U.S.C. § 102(b) to claim independent claim 1, and claims 56, 57 and 62-65 which depend therefrom. As claims 2, 58-61 and 66 also depend from independent claim 1, it is further believed that the rejections under 35 U.S.C. § 103(a) to claims 2 and 66, and 58-61, respectively should also be withdrawn, as discussed herein below.

The Examiner requested Applicant and Applicant's representative to submit proposed claim amendments for consideration. As the Examiner shall ascertain, amendments to the claims corresponding to the proposed amendments discussed during the Interview are provided herein below, as indicated herein above in the associated claim listing provided on separate sheets.

III. REJECTION UNDER 35 U.S.C. §§ 102/103(a) SHOULD BE WITHDRAWN

Claims 1, 56, 57 and 62-65 stand finally rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Patent No. 5,558,644 to Boyd et al. (hereinafter the "Boyd Patent"). Claims 2 and 66 stand finally rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Boyd Patent. Claims 58-61 stand finally rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Boyd Patent, in view of U.S. Patent No. 6,629,534 to St. Goar et al. (hereinafter the "St. Goar Patent"). Claim 67 stands finally rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Boyd Patent, in view of U.S. Patent No. 6,283,127 to Sterman et al. (hereinafter the "Sterman Patent").

Applicant respectfully asserts that the Boyd Patent, taken individually or in combination with the St. Goar Patent and/or the Sterman Patent, does not disclose, teach or suggest the subject matter recited in amended independent claim 1 for at least the reasons provided herein below.

In order for a claim to be rejected as anticipated under 35 U.S.C. § 102, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. Manual of Patent Examining Procedures, §2131; *also see Lindeman Machinenfabrik v. Am Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

"To reject claims in an application under Section 103, an examiner must show an unrebutted *prima facie* case of obviousness." *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1455 (Fed. Cir. 1998). The Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), stated:

> Under Section 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

Indeed, to sustain a rejection under 35 U.S.C. § 103(a), there must be some teaching, other than the instant application, to alter the prior art to arrive at the claimed invention. "The problem confronted by the inventor must be considered in determining whether it would have been obvious to combine the references in order to solve the problem." *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 679 (Fed. Cir. 1998).

The objective standard for determining obviousness under 35 U.S.C. § 103, as set forth in *Graham v. John Deere, Co.*, 383 U.S. 1 (1966), requires a factual determination to ascertain: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; and (3) the differences between the claimed subject matter and the prior art. Based on these factual inquiries, it must then be determined, as a matter of law, whether or not the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the alleged invention was made. *Graham*, 383 U.S. at 17. Courts have held that there must be some suggestion, motivation or teaching of the desirability of making the combination claimed by the applicant (the "TSM test"). *See In re Beattie*, 974 F.2d 1309, 1311-12 (Fed. Cir. 1992). This suggestion or motivation may be derived from the prior art itself, including references or disclosures that are known to be of special interest or importance in the field, or from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

Although the Supreme Court criticized the Federal Circuit's application of the TSM test, *see KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, (2007) the Court also indicated that the TSM test is not inconsistent with the *Graham* analysis recited in the *Graham v. John Deere* decision. *Id.*; *see In re Translogic Technology, Inc.*, No. 2006-1192, 2007 U.S. App. LEXIS 23969, *21 (October 12, 2007). Further, the Court underscored that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR*, 127 S. Ct. at 1741. Under the precedent established in *KSR*, however, the presence or absence of a teaching, suggestion, or motivation to make the claimed invention is merely one factor that may be weighed during the obviousness determination. *Id.* Accordingly, the TSM test should be applied from the perspective of a person of ordinary skill in the art and not the patentee, but that person is creative and not an automaton, constrained by a rigid framework. *Id.* at 1742. However, "the reference[s] must be viewed without the benefit of hindsight afforded to the disclosure." *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994).

The prior art cited in an obviousness determination should create a reasonable expectation, but not an absolute prediction, of success in producing the claimed invention. *In re O'Farrell*, 853 F.2d. 894, 903-04 (Fed. Cir. 1988). Both the suggestion and the expectation of success must be in the prior art, not in applicant's disclosure. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1207 (Fed. Cir. 1991) (citing *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988)). Further, the implicit and inherent teachings of a prior art reference may be considered under a Section 103 analysis. *See In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995).

Secondary considerations such as commercial success, long-felt but unsolved needs, failure of others, and unexpected results, if present, can also be considered. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983). Although these factors can be considered, they do not control the obviousness conclusion. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988).

To establish obviousness, the prior art references must be evaluated as a whole for what they fairly teach and neither the references' general nor specific teachings may be ignored. *Application of Lundsford*, 357 F.2d. 385, 389-90 (CCPA 1966). A reference must be considered for all that it teaches, not just what purportedly points toward the invention but also that which teaches away from the invention. *Ashland Oil, Inc. v. Delta Resins & Refractories*, 776 F.2d. 281, 296 (Fed. Cir. 1985).

Amended independent claim 1 recites, *inter alia*, a cutting arrangement, a catheter, and a grasping arrangement, wherein **the grasping arrangement is separate from the cutting arrangement**, and the catheter comprises **an opening in which the grasping arrangement constrains the movement of the at least one chord *and* in which the cutting arrangement is configured to sever the at least one chord**.

For example, as shown in Fig. 4A and described in para. [0037] of the above-identified application which illustrates an exemplary embodiment thereof, the catheter 20 comprises a notch (opening) 24 in which a wire 30 can constrain a movement of a chord 10, and in which the blade 28 is configured to sever the chord 10.

In contrast, the catheter described in the Boyd Patent does not teach, suggest or disclose a catheter comprising an opening in which the grasping arrangement constrains the movement of the at least one chord ***and in* which** the cutting

arrangement can be configured to sever the at least one chord, as explicitly recited in amended independent claim 1.

Rather, the Boyd Patent describes a catheter 10 through which forceps 71 and cutting means 65 having blades 68, 69 are provided. (See, e.g., Boyd Patent, Fig. 5; and col. 13, lns. 49-52). The grasping and the cutting actions in the Boyd Patent are performed ***outside*** any opening of the catheter 10. Even if it were possible for the forceps 71 to grasp a chord and then retract the chord into the discharge port 41 of the occluding catheter 10 prior to any severing of a chord, *clearly*, there is no room whatsoever for cutting means 65 with blades 68, 69 to perform any cutting of a chord within the discharge port 41 or the inner lumen 40 of the occluding catheter 10 to which to the discharge port 41 corresponds. Certainly, the Boyd Patent does not even mention such possibility, much less describe it.

In addition, the Boyd Patent specifically describes that the "[d]ue to its size and condition, the aortic valve 66 will usually have to be cut into smaller sections, such as section 70 as shown, so that it will fit within the inner lumen 40 of the occluding catheter 10 in order to remove the valve material from the patient." (Boyd Patent, col. 13, lns. 55-59). The Boyd Patent goes on to say that "[t]he cutting means 65 may have to be withdrawn from the occluding catheter 10 before large severed portions of the aortic valve 66 can be removed by forceps 71." (*Id.*, col. 13, ln. 65 – col. 14, ln. 1). Thus, as described in the Boyd Patent itself, there is likely not enough room for the removal of severed portions of the aortic valve 66 until the cutting means 65 have been withdrawn (e.g., removed or extended from) from the occluding catheter 10. It certainly follows that there is clearly not enough room to perform any severing whatsoever within the

inner lumen 40 of the occluding catheter 10, much less severing a chord being constrained by forceps 71.

Indeed, not only is it not possible to grasp and cut a chord within any opening of the catheter described in the Boyd Patent, but the sections of the Boyd Patent described herein above actually ***teach away*** from grasping and cutting within an opening of the catheter. (*See*, e.g., *id.*, col. 13, lns. 55-59 and col. 13, ln. 65 – col. 14, ln. 1). Moreover, the Boyd Patent further describes that "[a]n angioscope 67 is likewise advanced through the inner lumen 40 until the distal end thereof extends out of the distal end of the occluding catheter 10 [and that the] guidance and operation of the cutter 65 is controlled by the physician or other operator while observing the cutter through the angioscope 67." (See, *id.*, col. 13, lns. 46-55, and Fig. 5). This guidance, as described in the Boyd Publication, can only be possible if the cutter 65 also extends out of the distal end of the occluding catheter, thereby also *teaching away* from cutting within an opening of the catheter. Indeed, the Boyd Publication continues by indicating that "[d]uring the procedure a continuous flow of clear liquid . . . is maintained to facilitate observation of the region by the operator using the angioscope 67" (*id.*, col. 14, lns. 1-5), which, as one having ordinary skill in the art would appreciate, indicates a need for the angioscope 67 to see through a region that would otherwise be filled with blood, such region being *outside* of the catheter and *not within an opening* thereof.

Accordingly, Applicant respectfully asserts that not only does the Boyd Patent fail to teach, suggest or disclose the subject matter recited in amended independent claim 1, the Boyd Patent also clearly ***teaches away*** from a catheter comprising an opening in which the grasping arrangement constrains the movement of the at least one chord ***and***

in which the cutting arrangement can be configured to sever the at least one chord, as explicitly recited in this amended independent claim of the above-identified application. The St. Goar Patent and the Sterman Patent do not cure these deficiencies of the Boyd Patent, and the Examiner does not allege that they do.

The claims which depend from amended independent claim 1 are also believed to be patentable over the Boyd Patent, taken alone or in combination with the St. Goar Patent and the Sterman Patent at least based on the same arguments as provided herein above with respect to amended independent claim 1.

Therefore, for at least the reasons described herein above, Applicant respectfully asserts that the rejection of independent claim 1, and claims 56, 57 and 62-65 which depend therefrom, under 35 U.S.C. § 102(b) as being allegedly anticipated by the Boyd Patent should be withdrawn. Further, for at the reasons described herein above, Applicant respectfully asserts that the rejections under 35 U.S.C. § 103(a) of claims 2 and 66. claims 58-61, claim and 67, all of which depend from independent claim 1, as allegedly being unpatentable over the Boyd Patent, the Boyd Patent in view of the St. Goar Patent, and the Boyd Patent in view of the Sterman Patent, respectively, should also be withdrawn.

With further respect to claim 60, this claim recites, *inter alia*, "a distal end of the wire comprises a hook-shaped portion." In the Final Office Action, the Examiner admits that the "Boyd [Patent] do[es] not teach a wire grasping element" and asserts that the "St. Goar [Patent] disclose[s] a cardiac catheter with multiple capture coils [that] may be loops of nitinol", relying on Fig. 32A, # 60 & 62, and col. 25, lns 45-55 of the St. Goar Patent. (Final Office Action, p. 4, ln. 22 – p. 5, ln. 1). The Examiner then contends that

"[t]he loops being circular, they have portions that are at an acute angle to the opening of the catheter [and that it] would have been obvious . . . to use the loops" of the St. Goar Patent with the device described in the Boyd Patent "to capture tissues, such as chordae, during a cardiac procedure." (*Id.*, p. 5, lns. 1-4).

Applicant respectfully disagrees. As an initial matter, the St. Goar Patent does not teach *a grasping member comprising a wire, a distal end of which comprises a hook-shaped portion*, as explicitly recited in claim 60 of the above-identified application. Rather, the St. Goar Patent specifically describes capture coils 60, 62, as shown in FIGS. 32A and 32B of thereof. (*See*, e.g., the St. Goar Patent, Col. 25, lns. 46-49). As shown in FIGS. 32A and 32B of this publication, and described in the corresponding text of the specification thereof, the coils 60, 62 have a helical configuration. Clearly, a coil is not equivalent to a **hook-shape**, as explicitly recited in claim 60 of the above-identified application, nor does the Examiner assert that it is. Rather, in response to Applicant's arguments, the Examiner contends that "a wire can be broadly interpreted as a thin strip [and that] all of the graspers disclosed can be and have been interpreted as a thin strip." (See, e.g., Final Office Action, p. 7, lns, 12-18). Thus, even assuming, *arguendo*, that this assertion by the Examiner is correct, the Examiner still does not assert that any of the references relied on in the Final Office Action teach a distal end of the wire comprising a hook-shaped portion, as explicitly recited in claim 60.

Moreover, it is respectfully asserted that one having ordinary skill in the art would not have attempted to use the coils of the St. Goar Patent with the catheter described in the Boyd Patent at least because the Boyd Patent describes that "severed portions of the aortic valve 66 can be removed by forceps 71" (Boyd Patent, col. 13, ln. 67 – col.

14, ln. 1), and the coils shown and described in the St. Goar Patent are not configured, or even capable of performing such procedure.

With further respect to claims 62 and 63, these claims recite, *inter alia*, that the grasping arrangement comprises a pincer member that is **rotatably coupled** to the catheter, and that the grasping arrangement comprises two pincer members that are **rotatably coupled** to the catheter, respectively. In the Final Office Action, the Examiner alleges that the blades 68 and 69 of the Boyd Patent (in Fig. 5 thereof) are arranged in a pincer configuration, and as rotatable relative to the catheter. (See, e.g., Final Office Action, p. 2, lns. 16-17). However, claims 62 and 63 recite that the pincer member(s) is/are **rotatably coupled** to the catheter. The blades 68, 69 of the Boyd Patent are not coupled to the catheter, and are positioned with respect to the chord independently of the catheter, much less **rotatably coupled** to the catheter, as explicitly recited in claims 62 and 63.

In response to Applicant's arguments, the Examiner contends that the recitation of "'coupled' is broadly interpreted as directly or indirectly connected by structure or function" and that "pincers 97 and 98 [shown in Figure 11 of the Boyd Patent] are delivered through the lumen of the catheter [and] are therefore coupled to the catheter." (*Id.*, p. 7, ln. 19 – p. 8, ln. 2). However, even with such interpretation, the pincers 97 and 98 shown in Fig. 11 of the Boyd Patent as rotating relative to the shaft of the cutting system 96, and not the catheter. Indeed, the pincers 97 and 98 are not even indirectly connected to the shaft by structure or function, rather they are connected to the cutting system 96, which itself is merely provided through the catheter. Therefore, Applicant respectfully asserts that claims 62 and 63 are patentable over the Boyd Patent. The St.

Goar Patent and the Sterman Patent do not cure these deficiencies, and the Examiner does not allege that they do.

With further respect to claim 64, this claim has been amended herein above and now recites, *inter alia*, "a stabilizing arrangement configured to at least partially constrain a motion of the catheter relative to a location within a chamber of a heart and extend longitudinally **past an edge of the catheter** to a ventricle." In the Final Office Action, the Examiner asserts that the Boyd Patent allegedly shows in Figure 5 that the catheter includes an inflatable balloon (# 11) for stabilizing the catheter within the heart in rejecting this claim. (*Id.*, p. 2, lns. 19-21). The Examiner further contends, in response to Applicant's arguments, that the balloon 11 shown in the Boyd Patent is allegedly capable of extending to an apex of the ventricle.

Applicant respectfully disagrees. As an initial matter, as Applicant explained during the Interview, the balloon 11 shown in the Boyd Patent is not capable of extending longitudinally to a ventricle at all, much less extend longitudinally **past an edge of the catheter** to a ventricle. Rather, the balloon 11 shown in the Boyd patent extends laterally/radially from the catheter. Nevertheless, to expedite the prosecution of the above-identified application and not for any reason related patentability of claim 64, this claim has been amended herein above to clarify the subject matter recited therein and address the Examiner's comments. In particular, claim 64 has been amended to recite, inter alia, that the stabilizing arrangement is configured to extend longitudinally **past an edge of the catheter** to a ventricle. Clearly, the balloon 11 shown in the Boyd Patent is in no way configured to extend longitudinally **past an edge of the catheter** to a ventricle, as explicitly recited in amended claim 64 of the above-identified application.

IV. NEW CLAIMS

New claims 70-73, which depend from amended independent claim 1, have been added herein above to recite certain subject matter which Applicant believes includes separately novel features. Support for new claims 70-73 can be found in the originally-filed application, including the specification, drawings and/or claims thereof. (*See*, e.g., Specification of the above-identified application, paras. [0037] - [0039] and [0042], and Figures 4A and 4B).

In particular, new claim 70 depends from amended claim 64 and recites, *inter alia*, that the stabilizing arrangement is further configured to extend longitudinally to an apex of the ventricle. New claims 71-73 depend from amended independent claim 1 and recite, inter alia, that the cutting arrangement is further configured to sever the at least one chord only within the opening, that the grasping arrangement and the cutting arrangement are longitudinally coupled to one another, and that the cutting arrangement is further configured to move only in a parallel dimension with respect to the grasping arrangement to facilitate the severing of the at least one chord in the opening, respectively.

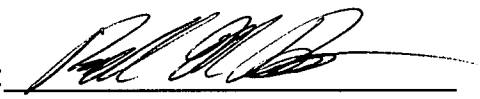
Applicant respectfully asserts that new claims 70-73 are allowable over the Boyd Patent, the St. Goar Patent and the Sterman Patent, either taken alone or in combination. It is respectfully requested that a confirmation of patentability of these claims be provided in the next communication for this application to Applicant's representatives.

V. CONCLUSION

In light of the foregoing, Applicant respectfully submits that pending claims 1, 2 and 56-73 are in condition for allowance. Prompt consideration, reconsideration and allowance of the present application are therefore earnestly solicited. If any issues remain outstanding, the Examiner is invited to contact the undersigned via the telephone number provided herein below.

Respectfully submitted,

Date: April 22, 2010

By: 

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